

**Notice of Allowability**

Application No.

09/933,548

Examiner

Sally A Sakelaris

Applicant(s)

OGDEN ET AL.

Art Unit

1634

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/26/2004.
2. ☒ The allowed claim(s) is/are 2-5,7-9,15,39,41 and 43-48.
3. ☒ The drawings filed on 20 August 2001 and 31 October 2003 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Please amend the claims as follows:

a. Amend claim 3 as follows:

3. A method of identifying the presence of [and] metastatic [potential of] prostate cancer in a human patient comprising the steps of:

(i) obtaining a sample containing mRNA from a test sample of prostate cells from the patient; and

(ii) detecting the presence or absence of Pax 2 mRNA expression which is associated with metastatic prostate cancer; and

(iii) diagnosing the presence of metastatic prostate cancer in the event that the presence of Pax 2 mRNA expression which is associated with metastatic prostate cancer is detected in the test sample.

b. Amend claim 39 as follows:

39. A method according to claim 2 wherein no Pax 2 mRNA is detectable in the sample of non-cancerous [or non-metastatic] cells.

c. Amend claim 41 as follows:

41 A method according to claim 3 wherein no Pax 2 mRNA is detectable in the sample of non-cancerous [or non-metastatic] cells.

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d. It is further noted that the title has been amended to read:

--Methods of diagnosing prostate cancer through the detection of the presence or absence of Pax 2 mRNA--

**THE FOLLOWING IS AN EXAMINER'S STATEMENT OF REASONS  
FOR ALLOWANCE:**

The present invention is found to be allowable subject matter as its presentation of a method of diagnosing prostate cancer through the detection of the presence or absence of Pax 2 mRNA expression represents a contribution over the prior art that lacks any such detection method.

The closest prior art made of record is as follows:

Gruss et al. teach a therapeutical or diagnosing agent that contains as active substance at least one nucleic acid which hybridizes with a pax gene, at least a pax protein, or at least one antibody against a pax protein or one of its derivatives. The reference does not teach Pax 2 or any pax gene to be diagnostic of prostate cancer. (WO 94 03196 A (Max Planck Gesellschaft; Gruss Peter (DE); Maulbecker Catharina (C) 17 February 1994).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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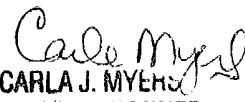
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris

  
8/3/2004

  
CARLA J. MYERS  
PRIMARY EXAMINER